JAN 24 2000

K993533

Attachment F

510 (k) Summary

Date

October 15, 1999

Submitter and Contact Person

Cardiac Science, Inc.
1176 Main Street, Building "C"
Irvine, CA 92614

Contact. Stan Tillman, Dir. RA/QA
Phone: 949/587-0357, ext. 238

Device Name

Trade Name	Common/Classification Name
Powerheart® AECD®	Defibrillator, Automatic, External

Predicate Device

Powerheart® AECD® (K970741).

Device Description

The Powerheart monitors a patient's cardiac electrical activity and detects and treats ventricular tachyarrhythmias. The patient is connected to the device by a patient cable which is attached to both a set of ECG electrodes and a set of defibrillation electrodes. The defibrillation electrodes can be positioned on the patient sternum-apex or anterior-posteriorly. The operator can program the device during set up to use either the ECG electrodes or the defibrillator electrodes to sense ECG.

The Powerheart uses a combination of rate and, if programmed by the physician, morphology to determine the presence of shockable arrhythmias. When a shockable arrhythmia is detected, the system delivers cardioversion and/or defibrillation energy through defibrillator electrodes to restore normal cardiac rhythm.

Should the arrhythmia continue, the Powerheart will deliver additional electrical countershocks after each subsequent evaluation and programmed delay. Depending upon the programmed parameters as prescribed by the physician, the Powerheart may deliver a maximum of nine pulse sequences. In the event that nine pulse sequences have been delivered, the Powerheart will not automatically deliver any further therapy until: 1) a new shockable rhythm is detected after 60 consecutive seconds of non-shockable rhythm is presented, or 2) the device is reset manually. The energy levels for each individual countershock are also programmed into the device per the physician's prescription.

Continued on next page

Intended Use

The Powerheart AECD is intended to acquire the electrocardiograph rhythm for the detection of, and to provide treatment for, ventricular tachyarrhythmias of in-hospital patients who are at risk of Sudden Cardiac Arrest.

Comparison Table

The modified Powerheart® has the same technological characteristics as the unmodified device which previously received 510(k) clearance as shown in the table below:

Feature	Predicate Device	Candidate Device
Primary Component	Powerheart proprietary AECD® Arrhythmia Detection Software (cleared under K970741 and also cleared separately under K982710)	Same
Major Components	11. defibrillator 12. defibrillation electrodes 13. ECG electrodes (off-the-shelf) 14. patient cable 15. computer system 16. control panel 17. display monitor 18. chart recorder (printer) 19. event recorder 20. ECG out cable	Same
Input Data	Electrocardiogram (ECG)	Same
Output	Delivery of shock	Same
Maximum Energy	360 Joules	Same
Defibrillation Waveform and Charging Time	Per AAMI DF2-1996	Same
ECG Signal Input	Defibrillation electrodes or bipolar ECG electrodes	Same
Operating Modes	5. Automatic, 6. Advisory, 7. Manual and 8. Program	Same
Physician Programmable Parameters	4. Patient ID number 5. Detection criteria, and 6. Therapy criteria	Same

Continued on next page

Non-clinical Tests

Based on the non-clinical performance testing, the device was concluded is as safe and effective, as performs as well as or better than the predicate device.

Summary of Performance Testing

- System Validation
- Observation of Requirements Implementation
- Analysis Tests
- Battery System Tests
- Defibrillation Related Performance
- Alarm System Tests
- Environmental Testing
- Electrical Safety Testing
- Functional Safety Testing
- Electromagnetic Compatibility Testing (EMC)
- ECG Channel/Defibrillator Pad ID
- Quality and Reliability
- Human Factors
- System Software Validation and Verification
- Arrhythmia Detection Software Verification and Validation

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 2000

Mr. Stan E. Tillman
Cardiac Science Inc.
16931 Millikan Avenue
Irvine, CA 92606

Re: K993533
Powerheart® External Cardioverter Defibrillator with RHYTHMx ECD™ Software
Regulatory Class: III (three)
Product Code: 74 MVK, MKJ, LDD
Dated: January 13, 2000
Received: January 14, 2000

Dear Mr. Tillman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment B

Indications for Use Statement

510(k) Number (if known)	K993533
Device Name	Powerheart® AECD®
Indications for Use	The Powerheart AECD is intended to acquire the electrocardiograph rhythm for the detection of, and to provide treatment for, ventricular tachyarrhythmias of in-hospital patients who are at risk of Sudden Cardiac Arrest.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Clearance of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number _____

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)